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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/921,533	09/02/1997	PERTTI TORMALA	2880/27	9610

26646 7590 11/25/2002

KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/921,533

Applicant(s)

TORMALA ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment E, dated 9-10-02 is acknowledged.

Status of Claims

Claims 1 and 16 have been amended. Claims 1-22 are pending.

The following rejection has been maintained for reasons of record:

Claim Rejections - 35 U.S.C. § 103

1. Claims 1-8 and 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent No. 5,084,051 to Tormala et al (hereafter '051).

Instant claims 1 and 16 recite a biodegradable and bioactive composite material for surgical osteosynthesis applications comprising: 1) at least one resorbable polymeric matrix component, 2) at least one oriented resorbable polymeric reinforcing component and III) at least one bioceramic or bioglass reinforcing component mixed with said matrix component. Claim 16 further requires that the diameter of the oriented component II is greater than the diameter of the particle size of the bioceramic component.

'051 teaches surgical biocomposite material suitable for bone surgical applications comprising a polymeric reinforcing element and bioceramic element, wherein the polymeric reinforcing element is a mixture of polymers or polymer and porous or non porous bioceramic material (abstract, lines bridging cols. 1 and 2; col. 3, lines 14-53; col. 4, lines 19-68, col. 5-6, col. 8, lines 61-68, col. 9-10). The reinforcing polymer is in the form of reinforcing fibers and the resulting composite has good mechanical strength and integrity and is easy to handle. '051 teaches various methods of manufacturing the composite as claimed in the instant invention and

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the addition of additives that facilitate bone growth and /or antibiotics in the composite material. In particular, the description of the biocomposite of Fig. 1a shows that a plate like composite is formed of a bioceramic and a polymer, which is reinforced with a fabric of fibers. Thus, the description of biocomposite meets the instant biocomposite material.

Examiner notes that in the instant case, both the matrix and reinforcing polymer could be the same material such as poly-lactide. '051 also teach that the second material component is made of polymeric material such as poly-lactide. Accordingly, the second component of '051 meets the claim requirement of matrix and reinforcing polymer.

'051 do not specifically teach a polymer matrix and an oriented polymeric reinforcement component. However, 'o51 suggests that the reinforcement element structures can be applied as oriented fibers (col. 8, lines 62-68 and col. 9, lines 5-10). Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare a biocomposite of '051 where in the reinforcing elements are oriented on the bioceramic and polymeric components, because'051 suggests that the biocomposite so achieved shows unexpectedly high strength.

'051 discussed above do not teach the claimed diameter of the reinforcing elements. However, '051 teach using different fibers, such as short, felt, non-woven fibers etc., (col. 8, lines 62-68 and also examples). '051 teaches the reinforcing elements to give the required strength to the biocomposite, while at the same time allowing for maximum in growth of bone tissue (col. 7). Therefore, it is the position of the examiner that optimizing the parameters such as diameter or thickness of the fibers of reinforcing polymer as well as the size of the bioceramic particles is well within the scope of ordinary skill in the art, such that the composite allows for

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the in growth of the bone and fibers impart good mechanical strength to the composite. Further, '051 suggest using powders of bioceramics in the manufacture of biocomposites such that the biocomposite material that is not too ductile or too tough can be achieved.

2. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent No. 5,084,051 to Tormala et al (hereafter '051) as applied to claims 1-8 and 11-22 above, and further in view of Bonfield et al.

Tormala discussed above does not teach the volume fraction of bioceramic as claimed in the instant invention. Bonfield et al teaches bone composites containing hydroxyapatite and polyethylene composites of 0.3-to 0.5 volume fraction, which imparts fracture toughness to the composite. Accordingly, it would have been obvious for one of a skilled artisan to machine the bone composites having a volume fraction because Bonfield teaches that between the above volume fractions the composites possess increased toughness and strength of the composite and have comparable mechanical properties with that of the bone.

Response to Arguments

Applicant's arguments filed 9-10-02 have been fully considered but they are not persuasive.

Applicants argue '051 do not anticipate instant invention because the reference fails to disclose the newly added limitation "oriented reinforcing element". In response to the amendment, examiner has withdrawn anticipation rejection of the previous action, over US

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5,084,051. However, the rejection of claims 1-8 and 11-22 as being obvious over 5,084,051 and claims 9 and 10 as being obvious over '051 in view of Bonfield are maintained.

Applicants argue that '051 do not suggest the instant limitation, "oriented reinforcing element". However, '051 suggest that the reinforcement element structures can be applied as oriented fibers (col. 8, lines 62-68 and col. 9, lines 5-10). Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare a biocomposite of '051 where in the reinforcing elements are oriented on the bioceramic and polymeric components, because '051 suggests that the biocomposite so achieved shows unexpectedly high strength.

With respect to the teachings of Bonfield et al, applicants argue that the reference does not teach "oriented reinforcing element" and therefore does not overcome the deficiencies of '051. However, this argument is not persuasive because, as explained in the previous paragraph, '051 is not deficient in teaching the limitation and instead suggests oriented reinforcing element for high strength of the biocomposite material. Therefore, the rejection is deemed to be proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

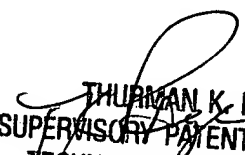
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala
Examiner
Art Unit 1615

November 21, 2002



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600